

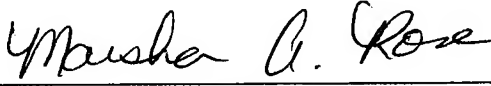
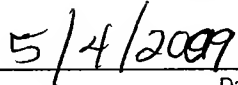
Doc Code: AP.PRE.REQ

PTO/SB/33 (01-09)

Approved for use through 02/28/2009. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional)	
		1694.0630003/JMC/M-R/KHR	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on _____ Signature _____ Typed or printed name _____	Application Number	Filed	
	10/801,951	March 17, 2004	
	First Named Inventor		
	William F. DeGRADO		
	Art Unit	Examiner	
	1617	CHONG, Yong Soo	
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.			
This request is being filed with a notice of appeal.			
The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.			
I am the			
<input type="checkbox"/>	applicant/inventor.	Signature	
<input type="checkbox"/>	assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)	Marsha A. Rose	
<input checked="" type="checkbox"/>	attorney or agent of record. Registration number 58,403	Typed or printed name	
<input type="checkbox"/>	attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____	(202) 371-2600	
		Telephone number	
			
		Date	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.			

☒ *Total of one (1) forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

974210v1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

DeGRADO *et al.*

Appl. No.: 10/801,951

Filed: March 17, 2004

For: **Facially Amphiphilic Polymers and
Oligomers and Uses Thereof**

Confirmation No.: 2895

Art Unit: 1617

Examiner: CHONG, Yong Soo

Atty. Docket: 1694.0630003/JMC/M-R/KHR

Arguments to Accompany the Pre-Appeal Brief Request for Review

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Mail Stop AF

Sir:

Applicants hereby submit the following Arguments, in five (5) or less total pages, as attachment to the Pre-Appeal Brief Request for Review (Form PTO/SB/33).

Summary of Request

The Examiner's final rejection of claims 16-48 and 67-73 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1, 4-8, 11, 14, 15, 20-22, and 26 of U.S. Patent No. 7,173,102 B2 ("the '102 patent") is improper. The Examiner has not established a case of obviousness-type double patenting. In particular, the Examiner has neither shown (1) that the same invention is being claimed twice nor (2) that the invention of claims 16-48 and 67-73 is merely an obvious variation of the invention of claims 1, 4-8, 11, 14, 15, 20-22, and 26 of the '102 patent. Accordingly, Applicants respectfully request that the obviousness-type double patenting be withdrawn.

Arguments

The obviousness-type double patenting rejection over claims 1, 4-8, 11, 14, 15, 20-22, and 26 of the '102 patent is improper. Specifically, the Examiner has not established a case of obviousness-type double patenting. The Federal Circuit has articulated two inquiries which must be made in determining whether a rejected claim is unpatentable under the

Atty. Dkt. No. 1694.0630003/JMC/M-R/KHR

judicially created doctrine of obviousness-type double patenting, also known as nonstatutory double patenting. *General Foods v. Studiengesellschaft Kohle mbH*, 23 USPQ2d 1839, 1843 (Fed. Cir. 1992)(citing *In re Vogel*, 422 F.2d 438, 439 (C.C.P.A. 1970)); *see also*, *Manual of Patent Examining Procedure*, 8th edition, revision 7, § 804, pp. 800-21-22 (July 2008). The court defines these inquiries as follows:

Is the same invention being claimed twice? If the answer to that is no, a second question must be asked: Does any claim in the application define merely an obvious variation of an invention claimed in the patent asserted as supporting double patenting? If the answer to that question is no, there is no double patenting.

General Foods, 23 USPQ2d at 1843. In addition, the court emphasized that where a "rejected claim defines *more* than an obvious variation, it is *patentably distinct*." *Id.* (emphasis in original).

The Same Invention is Not Being Claimed Twice

Pending claims 16-48 and 67-73 are directed to *a method of treating a microbial infection in an animal*, the method comprising administering to the animal an effective amount of a pharmaceutical composition comprising an amphiphilic oligomer, structurally defined in the claims, and a pharmaceutically acceptable carrier or diluent. A microbial infection is an invasion and multiplication of microorganisms in body tissues of an animal. *See* Dorland's Medical Dictionary for Healthcare Consumers (submitted as Exhibit A with Reply filed October 27, 2008). Thus, pending claims 16-48 and 67-73 are directed to the use of oligomers to treat the invasion and multiplication of microorganisms in *body tissues* of an animal. In contrast, claims 1, 4-8, 11, 14, 15, and 20-22 of the '102 patent are directed to a polymer or oligomer of a specific formula; and claim 26 is directed to a method of killing microorganisms comprising providing a substrate having disposed thereon a contact killing, facially amphiphilic polymer or oligomer; and placing the facially amphiphilic polymer or oligomer disposed thereon on the substrate in contact with a microorganism to allow formation of pores in the cell wall of the microorganism. While there is some overlap in the structural formulae of the pending claims and the claims of the '102 patent, the claims of the '102 patent do not recite a method of treating a microbial infection in an animal. Therefore, the same invention is *not* being claimed twice.

The Pending Claims do not Define Merely an Obvious Variation

First, the presently claimed invention is directed to the use of oligomers to treat a microbial infection, *i.e.*, the invasion and multiplication of microorganisms in body tissues of an animal. In contrast, claims 1, 4-8, 11, 14, 15, and 20-22 of the '102 patent are directed to facially amphiphilic polymers and oligomers. A person having ordinary skill in the art (PHOSITA) would not have expected that the compounds of claims 1, 4-8, 11, 14, 15, and 20-22 of the '102 patent could be administered to an animal to treat the invasion and multiplication of microorganisms in body tissues of an animal. Therefore, claims 16-48 and 67-73 of the current application do *not* define an obvious variation of the invention of claims 1, 4-8, 11, 14, 15, and 20-22 of the '102 patent.

Second, claim 26 of the '102 patent is directed to a method of killing microorganisms, which requires providing a substrate having disposed thereon a contact killing, facially amphiphilic polymer or oligomer; and placing the facially amphiphilic polymer or oligomer disposed thereon on the substrate in contact with a microorganism to allow formation of pores in the cell wall of said microorganism. The Examiner has taken the term "substrate" as used in claim 26 of the '102 patent out of context. The Examiner stated that "the term 'substrate' broadly includes any surface in need of killing [a] microorganism, such as the skin or internal organs." (Office Action mailed February 2, 2009, page 4.) The law requires that the Examiner give claim 26 "[its] broadest reasonable interpretation *consistent* with the specification." MPEP § 2111, p. 2100-37 (quoting *Phillips v. AWH Corp.*, 75 USPQ2d 1321 (Fed. Cir. 2005) (emphasis added)). The disclosure of the '102 patent taken as a whole does not indicate that the term "substrate" encompasses living tissues. (*See e.g.*, the '102 patent, at col. 26, lines 47-62.) For instance, the disclosure of the '102 patent describes the use of polymers of the '102 patent as "a surface-mediated microbicide that only kills organisms in contact with the surface." (*Id.* at col. 26, lines 63-65.) Additionally, the disclosure of the '102 patent states that "any object that is exposed to or susceptible to bacterial or microbial contamination can be treated with these polymers." (*Id.* at col. 27, lines 5-6.) Moreover, claims 27 and 28, which depend from claim 26, further define "substrate" as wood, synthetic polymers, plastics, natural and synthetic fibers, cloth, paper, rubber and glass, all substrates that are *not* infected living surfaces. (*Id.* at col. 45, lines 23-31.) In fact, the '102 patent provides no guidance to a PHOSITA as to routes of administration to an animal, useful pharmaceutically acceptable carriers or diluents, how the polymers are metabolized, or any potential toxicity associated with administration to the animals. Thus, a PHOSITA would

not reasonably interpret the term "substrate", in view of the plain language of claim 26 and the specification of the '102 patent, to broadly encompass an infected *living* surface, such as the skin or internal organs.

Furthermore, a PHOSITA would not have expected a polymer or oligomer that functions as an antimicrobial agent, when attached or applied to a substrate, such as wood or cloth, to be effective in treating a microbial infection in an animal when administered to the animal, as recited by claims 16-48 and 67-73 of the current application. Dr. Nicolau, an expert in the field of infectious diseases, stated *inter alia*, that "a person of ordinary skill in the art would not necessarily expect a polymer shown to function as an antimicrobial agent when attached to or incorporated into an object to be effective in treating a microbial infection in an animal." (Declaration under 37 C.F.R. § 1.132 of David P. Nicolau, Pharm.D., FCCP, pp. 3-4, ¶8; *see also*, Amendment and Reply filed June 25, 2008.) Similarly, Dr. Bermudez, who has expertise in the field of biopolymers, opined that "a person of ordinary skill in the art would not conclude from [the] disclosure in the '102 patent the polymers would not be toxic and would be safe to be administered as a pharmaceutical composition to treat a mammal with a microbial infection." (Declaration under 37 C.F.R. § 1.132 of Harry Bermudez, Ph.D. filed June 25, 2008, p. 5, ¶ 9.) The Examiner has not established why a PHOSITA would expect that a polymer or oligomer that functions as an antimicrobial agent, when attached or applied to a substrate, such as wood or cloth, as recited in claim 26 of the '102 patent, would be effective in treating the invasion and multiplication of microorganisms in body tissues of an animal when administered to the animal, as recited in claims 16-48 and 67-73 of the above-captioned application. As such, claims 16-48 and 67-73 of the current application do *not* define an obvious variation of the invention of claim 26 of the '102 patent.

For at least these reasons, the pending claims do *not* define merely an obvious variation of the invention of claims 1, 4-8, 11, 14, 15, 20-22, and 26 of the '102 patent, and are therefore patentably distinct. Accordingly, the rejection of 16-48 and 67-73 under the judicially created doctrine of obviousness-type double patenting has been overcome, and Applicants respectfully request that the Panel reconsider and withdraw the rejection.

Conclusion

For the reasons set forth above, the Examiner has not established a proper case of obviousness-type double patenting rejection. Accordingly, Applicants respectfully request that the obviousness-type double patenting be withdrawn.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Marsha A. Rose
Attorney for Applicants
Registration No. 58,403

Date: 5/4/2009

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600
963254_5.DOC